

Appl. No. : 10/003,782  
Filed : October 31, 2001

## REMARKS

### A. Introduction

Applicants respectfully request reconsideration of this application. Claims 1-20 are pending in the application. Applicants have added new Claims 12-20 to further clarify the scope of Applicants' claimed invention. Applicants submit that this application is in condition for allowance, and Applicants earnestly request such action. Below, Applicants address each of the Examiner's reasons for rejection.

### B. All Claims are Patentable Over the Cited Reference

#### Funderburk et al. - § 102 Rejections

The Examiner rejected Claims 1, 2, 9 and 11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,520,938 to Funderburk et al. Applicants respectfully submit that Funderburk et al. does not qualify as prior art to the present application under § 102(b).

Funderburk et al. issued on February 18, 2003. Applicants filed the present application on October 31, 2001, more than fifteen months before Funderburk et al. issued. Therefore, Funderburk et al. did not issue more than one year before Applicants' filing date, as § 102(b) requires. Nevertheless, even if Funderburk et al. were prior art to the present application under § 102(b), Applicants respectfully submit that Claims 1, 2, 9 and 11 are allowable over Funderburk et al.

An anticipation rejection under § 102 requires that "every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Various preferred embodiments of the present application define, *inter alia*, a universal passive protector for an IV catheter. The protector comprises a hypodermic needle and an over-the-needle catheter, including a hub, disposed about the needle. The protector further comprises a hub trap including first and second arms, an elongate sheath, and a slider connected to a proximal end of the needle. The slider is movable along the sheath from a distal position to a proximal position. When the slider is in the distal position, the needle extends through a locking structure of the hub trap and retains the first and second arms in a closed position wherein the hub is trapped between the first and second arms. When the slider is in the proximal position, a

**Appl. No.** : 10/003,782  
**Filed** : October 31, 2001

distal tip of the needle is proximal of the locking structure, and the first and second arms are in an open position wherein the hub is released from the hub trap.

By contrast, Funderburk et al. discloses a medication infusion set. The infusion set comprises a soft cannula for subcutaneous delivery of a selected medication to a patient. The cannula protrudes from a cannula housing, and has a self-sealing septum mounted at an upstream end thereof. The cannula housing is initially assembled with an insertion hub. The hub has an elongated insertion needle extending through the septum and cannula for transcutaneously placing the cannula followed by separation of the insertion hub from the cannula housing. An infusion hub is then assembled with the cannula housing. The infusion hub includes a short infusion needle for coupling the cannula with the selected medication supplied from a source via a length of infusion tubing. The infusion hub includes a protective shroud plate protruding beyond a tip end of the infusion needle to minimize risk of patient contact therewith. The shroud plate is adapted for slide-fit reception into a matingly shaped slot formed in the cannula housing. Releasable latch members interlock the infusion hub with the cannula housing.

Funderburk et al. does not disclose a universal passive protector for an IV catheter having the features claimed in the present application. For example, Funderburk et al. does not disclose a slider connected to a proximal end of a needle, the slider being movable along a sheath from a distal position to a proximal position. The Examiner has identified the needle guide 34 of Funderburk et al. as a sheath, and the inserter hub 16 of Funderburk et al. as a slider. Applicants respectfully disagree that these components of Funderburk et al. could be considered a sheath and a slider, as described in the present application.

Applicants' sheath 34 provides a track along which Applicants' slider 38 is movable between a distal position and a proximal position. Because Applicants' slider is connected to a proximal end of the needle, movement of the slider along the sheath induces movement of the needle. As the slider moves from the distal position to the proximal position, it draws the needle into the sheath. When the slider reaches the proximal position, the needle is completely disposed within the sheath. The sheath protects patients and operators of Applicants' device from accidental needle sticks.

By contrast, the needle guide 34 of Funderburk et al. is press-fit mounted within the cannula 12 (col. 4, lns. 58-62). The insertion needle 18 extends from the inserter hub 16, through the needle guide 34 and through the cannula 12 (Figure 6). The inserter hub 16 is thus not

Appl. No. : 10/003,782  
Filed : October 31, 2001

movable along the needle guide 34, as Applicants' slider is movable along Applicants' sheath. Furthermore, when an operator withdraws the needle 18 of Funderburk et al. from the cannula 12, the needle 18 is not disposed within the needle guide 34 as Applicants' needle 40 is disposed within Applicants' sheath 34. On the contrary, the needle 18 of Funderburk et al. is completely separated from the needle guide 34 such that the sharp distal tip of the needle 18 is exposed and could potentially stick a patient or an operator of the infusion set (col. 5, ln. 54 to col. 6, ln. 18).

Since Funderburk et al. does not disclose a universal passive protector for an IV catheter having the features claimed in the present application, Applicants respectfully submit that independent Claim 1 is not anticipated by Funderburk et al. Dependent Claims 2, 9 and 11, which include the features of independent Claim 1, recite additional features of particular advantage and utility. Moreover, these claims are allowable for substantially the same reasons presented above. Funderburk et al. does not disclose all of the limitations of Claim 1, let alone the unique combinations of features recited by Claims 2, 9 or 11. Accordingly, Applicants respectfully request that the Examiner withdraw these rejections.

Funderburk et al. - § 103 Rejections

The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Funderburk et al. Applicants respectfully submit that Claim 8 is allowable over Funderburk et al.

In rejecting claims under § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, the following criteria must be met. There must be some suggestion or motivation found in the prior art, either in one or more references or in the knowledge generally available to one of ordinary skill in the art, to modify a prior art reference or to combine reference teachings to meet the limitations of the claim. Further, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); M.P.E.P. § 706.02(j). "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Inter. 1985); M.P.E.P. § 706.02(j).

Appl. No. : 10/003,782  
Filed : October 31, 2001

Applicants respectfully submit that Claim 8 is dependent upon Claim 7. The Examiner has indicated that Claim 7 recites allowable subject matter. Therefore, Claim 8, which includes all of the limitations of Claim 7, must also recite allowable subject matter. Accordingly, Applicants respectfully assert that Claim 8 is allowable over Funderburk et al., and Applicants respectfully request that the Examiner withdraw this rejection.

### CONCLUSION

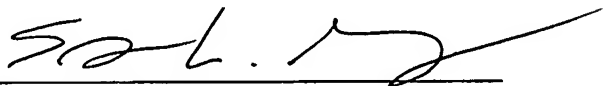
For the reasons presented above, Applicants respectfully submit that this application is in condition for allowance. If there is any further hindrance to allowance of the pending claims, Applicants invite the Examiner to contact the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 8-20-03

By:   
Scott Loras Murray  
Registration No. 53,360  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404

L:\DOCS\SLM\SLM-5626.DOC:sb 081903